FDA ADVISORY
No. 2024-0519

08 MAR 2024

TO: **ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC**

SUBJECT: **Public Health Warning Against the Purchase and Use of the Unregistered Medical Device Product "ETHICON® PROLENE™ POLYPROPYLENE ETHALLOY™ NEEDLE ALLOY"**

The Food and Drug Administration (FDA) warns all healthcare professionals and the general public **NOT TO PURCHASE AND USE** the unregistered medical device product:

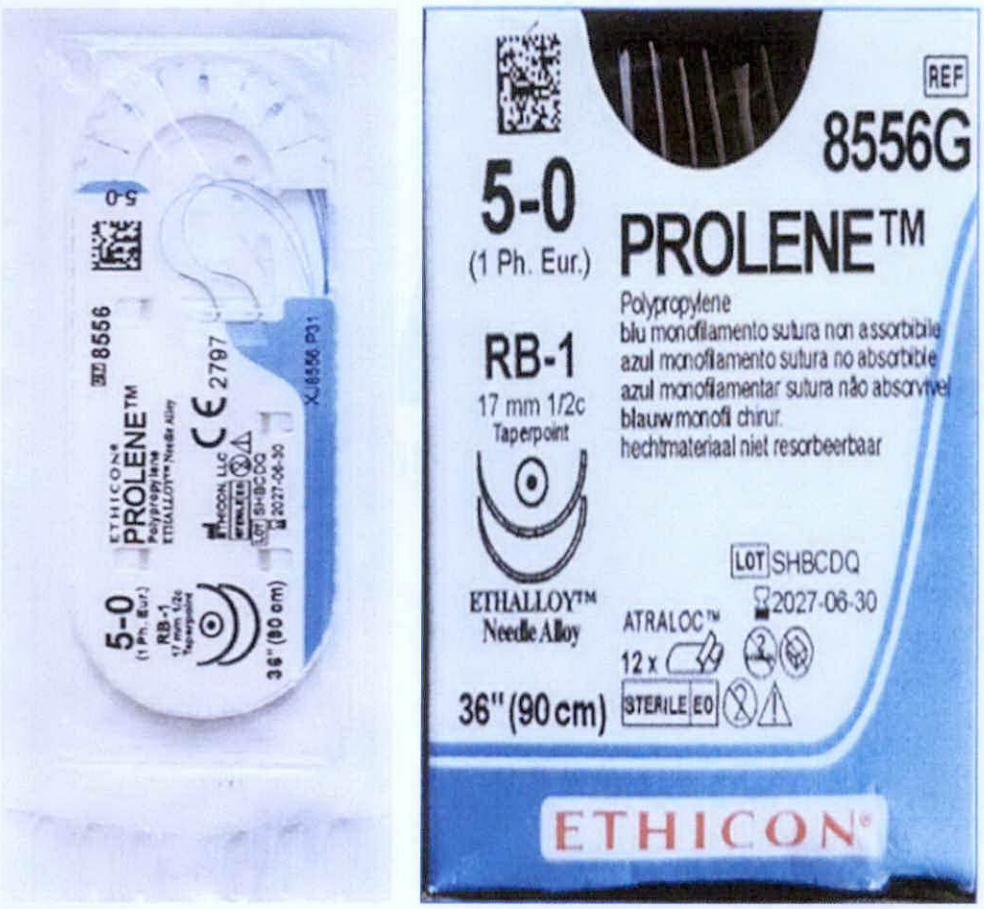

Figure 1. Unregistered Ethicon® Prolene™ Polypropylene Ethalloy™ Needle Alloy

The FDA verified through post-marketing surveillance that the above mentioned medical device product is not registered and no corresponding Product Registration Certificate has been issued. Pursuant to the Republic Act No. 9711, otherwise known as the "Food and Drug Administration Act of 2009", the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, non-consumer use, promotion, advertising or sponsorship of health product without the proper authorization is prohibited.

Furthermore, the FDA, in coordination with Johnson & Johnson (Philippines), Inc. verified that the above-stated medical device product is not part of their registered portfolio and there is no transaction history of the product concerned.

Since this unregistered medical device product has not gone through evaluation process of the FDA, the agency cannot assure its quality and safety.

In light of the foregoing, the public is advised not to purchase the violative product in the market.

All concerned establishments are warned not to distribute, advertise, or sell the said violative medical device product until the Product Registration Certificate is issued, otherwise, regulatory actions and sanctions shall be strictly pursued. Always check if a product has been registered with the FDA before purchasing it by making use of the embedded Search feature of the FDA website accessible at www.fda.gov.ph. You may also look for the FDA Registration number on the product label in the form of either CMDR-xxx, DVR-xxx, or MDR-xxx.

All Law Enforcement Agencies (LEAs) and Local Government Units (LGUs) are requested to ensure that this product is not sold or made available in the market or areas of jurisdiction.

The Bureau of Customs is urged to restrain the entry of this unregistered product.

For more information and inquiries about this advisory, kindly contact the FDA CDRRHR through e-mail at **cdrrhr@fda.gov.ph** indicating on the subject the concerned Advisory, or call **(02) 8857-1900 loc. 8301.**

To report any sale or distribution of unregistered medical device, contact the online reporting facility eReport through e-mail at **ereport@fda.gov.ph.**

Dissemination of this advisory to all concerned is hereby requested.

DR. SAMUEL A. ZACATE
Director General

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